## Special 510(k) Summary of Safety and Effectiveness:

## Device Modifications to the Long Length Gamma Nail

**Submission Information**

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| Name and Address of the Sponsor of the 510(k) Submission: | Howmedica Osteonics Corp<br>59 Route 17<br>Allendale, NJ 07401-1677 |
| Contact Person: | Karen Ariemma<br>Regulatory Affairs Specialist |
| Date of Summary Preparation: | July 10, 2001 |

**Device Identification**

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| Proprietary Name: | Long Length Gamma® Nail |
| Common Name: | Intramedullary Nail |
| Classification Name and Reference: | Intramedullary Fixation Rod, 21 CFR §888.3020 |

This Special 510(k) submission is intended to address a design modification to the predicate Long Length Gamma® Nail. The existing Long Length Gamma® Nail is an intramedullary rod intended to be used in the fixation of femoral fractures[1] occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intercondylar notch. The current design is cannulated, with a medial/lateral and anterior/posterior curve. The design modification involves changing the radius of curvature in the A-P plane. The modified device will allow the surgeon greater intraoperative flexibility in treating a variety of femoral fractures. The modified Long Length Gamma® Nails are substantially equivalent to the existing design of Long Length Gamma® Nail which was determined substantially equivalent via the 510(k) process. The materials used to manufacture the modified device are identical to those of the predicate. There is no change in intended use for the modified device when compared to the previously cleared product.

[1] Historically, Howmedica Osteonics has intended this product to be used in fracture management as a result of trauma, non-unions, mal-unions, pathological fractures, and impending pathological fractures.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 2001

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K012158
Trade/Device Name: Long Length Gamma® Nails
Regulation Number: 888.3020
Regulatory Class: II
Product Code: HSB
Dated: July 10, 2001
Received: July 11, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note:

this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General
Restorative and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K____

Device Name: Long Length Gamma® Nails

Indications For Use:

The intended use of the modified Long Length Gamma® Nail is identical to that of the predicate Long Length Gamma® Nail: the product is intended to be used in fixation of femoral fractures occurring from the base of the femoral neck extending distally to a point approximately 10 cm proximal to the intracondylar notch. Fracture types include basilar neck, intertrochanteric, subtrochanteric fractures and femoral shaft fractures. These femoral fractures may occur as a result of trauma, non-union, mal-union, pathological fractures, and impending pathological fractures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____

(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K012158